



EU DECLARATION OF CONFORMITY
According to Annex II and Annex III of Regulation (EU) 2017/745

GC EUROPE N.V.
Research Park
Interleuvenlaan 33
B-3001 Leuven
Belgium

SRN: BE-MF-000001608

We ensure and declare under our sole responsibility that the product :

Product Name	Fit Checker Advanced
Intended Purpose	VPES silicone for checking fit
Classification according to Annex VIII of the Regulation (EU) 2017/745	Class I, Rule 5
Article List	According to the Attachment
Basic UDI-DI	++J022MD0020JQ

to which this declaration relates is in conformity with the following standards or other normative documents :

EN ISO 13485:2016 Medical Devices –Quality Management Systems –
Requirements for Regulatory Purposes

and meets the provisions of Regulation (EU) 2017/745 concerning Medical Devices which apply to it, and is manufactured in accordance with the technical documentation.

Leuven, ...10/10/2022
Date

Mario Minale
Head of Regulatory Affairs
On behalf of GC EUROPE N.V.



LIST OF PRODUCTS

Basic UDI-DI	Article Code	EEP article code	New Article code	New EEP article code	Description
++J022MD0020JQ	004903	014403	10001025	10007493	GC FIT CHECKER ADVANCED, 1-1 Pack, (55g + 50g), B/C, White
++J022MD0020JQ	004904	014404	10001026	10007494	GC FIT CHECKER ADVANCED, Cartridges (2x62g), White